

09/12/03  
16711 U.S. PTO

# UTILITY APPLICATION

Attorney Docket No.: LOMACEN.015C5  
First Named Inventor: William J. Wechter  
Title: USE OF  $\gamma$ -TOCOPHEROL AND ITS OXIDATIVE  
METABOLITE LLU- $\alpha$  IN THE TREATMENT OF  
DISEASE  
Express Mail Label No.: EV 319 019 934 US

Direct all correspondence to Customer No.: 20995

Date: September 12, 2003

Page 1 of 2

03970 U.S. PTO  
10/661336  
09/12/03

## Mail Stop Patent Application

United States Patent and Trademark Office  
PO Box 1450  
Alexandria, VA 22313-1450

The following enclosures are transmitted herewith to be filed in the patent application of:

Inventor:

1. William J. Wechter

## APPLICATION ELEMENTS:

- (X) Specification in 56 pages.
- (X) Request for Interference in 3 pages.

## CONTINUITY INFORMATION:

Application	Relationship	Parent App. No.	Filing Date	Status
This Application	Continuation of	10/372,510	02/21/03	Pending
10/372,510	Continuation of	10/134,140	04/26/02	Issued
10/134,140	Continuation of	09/814,330	03/21/01	Issued
09/814,330	Continuation of	09/461,645	12/14/99	Issued
09/461,645	Continuation of	09/215,608	12/17/98	Issued

- (X) Incorporation by Reference. The entire disclosure of the prior applications is considered a part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

## OTHER APPLICATION PARTS:

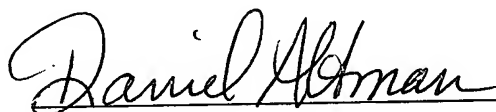
- (X) Return prepaid postcard.
- (X) A copy of the latest inventor signed Oath or Declaration from the parent application.

<b>UTILITY APPLICATION</b>	Attorney Docket No.: <b>LOMACEN.015C5</b>
	First Named Inventor: <b>William J. Wechter</b>
	Title: <b>USE OF <math>\gamma</math>-TOCOPHEROL AND ITS OXIDATIVE MATABOLITE LLU-<math>\alpha</math> IN THE TREATMENT OF DISEASE</b>
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<b>Direct all correspondence to Customer No.: 20995</b>	
Date: September 12, 2003 Page 2 of 2	

**FILING FEES:**

FEE CALCULATION				
FEE TYPE		FEE CODE	CALCULATION	TOTAL
Basic Utility		1001 (\$750)		\$750
Non-English Spec.		1053 (\$130)		\$0
Recordation Fee		8021 (\$40)	0 x 40 =	\$0
Excess Claims > 20	19 - 20 = 0	1202 (\$18)	0 x 18 =	\$0
Independent > 3	1 - 3 = 0	1201 (\$84)	0 x 84 =	\$0
Multiple Claim		1203 (\$280)		\$0
			<b>TOTAL FEE DUE</b>	<b>\$750</b>

(X) A check in the amount of \$750 is enclosed. Please charge any additional fees to Deposit Account No. 11-1410.



Daniel E. Altman  
Registration No. 34,115  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

Daniel E. Altman

MAIL STOP PATENT APPLICATION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

**Attorney Docket No. :** LOMACEN.015C5

**Applicant(s) :** Wiliam J. Wechter

**For :** USE OF  $\gamma$ -TOCOPHEROL AND ITS OXIDATIVE  
MATABOLITE LLU- $\alpha$  IN THE TREATMENT OF  
DISEASE

**Attorney :** Daniel E. Altman

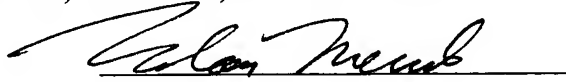
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**Date of Deposit :** September 12, 2003

I hereby certify that the accompanying

Transmittal letter; specification in 56 pages; Copy of Declaration; Request for  
Interference in 3 pages; Return Prepaid Postcard

are being deposited with the United States Postal Service "Express Mail Post Office to  
Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the  
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Nelson Merida

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	William J. Wechter	Group Art Unit Unknown
Appl. No.	:	Unassigned	
Filed	:	Herewith	
For	:	USE OF $\gamma$ -TOCOPHEROL AND ITS OXIDATIVE MATABOLITE LLU- $\alpha$ IN THE TREATMENT OF DISEASE	
Examiner	:	Unknown	

REQUEST BY APPLICANT OF INTERFERENCE PURSUANT TO 37 C.F.R. § 1.604(a)

United States Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

The Applicant herewith submits the above-named application having Claims 1-19, which correspond to or encompass Claims 1-3, 8-10, 15-32, and 51-57 of U.S. Patent Application No. 10/020,450 by Miller et al. The present application ultimately claims priority under 35 U.S.C. § 120 to U.S. Application No. 09/215,608, filed December 17, 1998, and contains substantially the same disclosure as that earlier application. Accordingly, the effective filing date of the present application is December 17, 1998, which is well before the earliest claimed priority date of the Miller et al. application.

PROVOCATION OF INTERFERENCE PURSUANT TO 37 C.F.R. § 1.604(a)Identification Of Other Application

Applicant requests that an interference be declared between the present application and U.S. Patent Application No. 10/020,450 by Miller et al. The Miller et al. application was published on October 3, 2002 as Publication No. 2002/0143049. Since the present application is

being filed within one year of this publication date, the requirements of 35 U.S.C. § 135(b)(2) have been met.

Proposed Count

Claims 1-3, 8-10, 15-32, and 51-57 in U.S. App. No. 10/020,450 by Miller et al. correspond to the claims of the present application. Accordingly, Applicant proposes that the count be all of the claims of the present application (i.e., Claims 1-19).

Identification Of Claims In Other Application Corresponding To The Proposed Count

Claims 1-3, 8-10, 15-32, and 51-57 of U.S. Application No. 10/020,450 by Miller et al. correspond to the proposed count. Although these claims are not identical to the proposed count, as described below, there is no patentable distinction between these claims and the proposed count.

Claims 1-3, 8-10, 16-18, 22, and 51-54 in Miller et al. are identical to Claims 1-3, 4-6, 7-10, 13, and 15-18 in the present application, respectively. Note that gamma-CEHC in Claim 8 of Miller et al. is synonymous with 6-hydroxy-2,7,8-trimethylchroman-2-propanoic acid in Claim 4 of the present application.

Claims 19-23 in Miller et al. are patentably indistinct from Claims 11-12 in the present application. Claims 19-23 recite “[a] method for treating and/or ameliorating the symptoms of a cerebral ischemic condition,” comprising administering a gamma-tocopherol enriched tocopherol composition comprising at least 80%, 85%, 90%, 95%, and 98% gamma-tocopherol, respectively. Claims 11-12 recited the same method comprising administering a gamma-tocopherol enriched tocopherol composition comprising at least 50% to 100%, and 55% to 95% gamma-tocopherol, respectively.

Claims 24-31 in Miller et al. are patentably indistinct from Claim 14 in the present application. Claims 24-31 recite “[a] method for treating and/or ameliorating the symptoms of a cerebral ischemic condition,” comprising administering a gamma-tocopherol metabolite enriched composition comprising at least 60%, 65%, 70%, 75%, 80%, 85%, 90%, and 95% gamma-tocopherol metabolite, respectively. Claim 14 recites the same method comprising administering a gamma-tocopherol metabolite enriched composition comprising 5% to 95% gamma tocopherol metabolite.

Claims 55-57 in Miller et al. are patentably indistinct from Claim 19 in the present application. Claims 55-57 recite “[a] method for treating and/or ameliorating the symptoms of a cerebral ischemic condition,” comprising administering a composition comprising a non-alpha tocopherol in the range of 1-1000 mg/kg, 1-50 mg/kg, and 10-100 mg/kg body weight, respectively. Claim 19 recites the same method comprising administering a composition comprising gamma-tocopherol at 20 mg/kg body weight.

Claim 32 of Miller et al. is patentably indistinct from Claim 3 of the present application. Claim 32 recites “[a] method for treating and/or ameliorating the symptoms of a cerebral ischemic condition,” comprising administering a gamma-tocopherol metabolite enriched composition comprising at least 98% gamma-tocopherol metabolite. Claim 3 recites the same method and encompasses a gamma-tocopherol metabolite enriched composition comprising at least 98% gamma-tocopherol metabolite.

#### Explanation Favoring Declaration of Interference

A basis exists for the declaration of an interference between the present application and U.S. Application No. 10/020,450 by Miller et al. As noted above, Claims 1-19 of the present application correspond to Claims 1-3, 8-10, 15-32, and 51-57 in the Miller et al. application.

#### Support in Specification for Claims of the Present Application

The specification of the present application provides support for all the claims of the proposed count. The methods recited in Claims 1-3 are supported by page 4, lines 20-26, page 6, line 14, and page 7, lines 29-30. Claims 1-3 are also supported by Example 28, which discloses the “treatment and prevention of neuropathological lesions.” See page 51. The specification also discloses a “compound 6-hydroxy-2,7,8-trimethylchroman-2-propanoic acid,” which supports Claim 4. See Page 5, lines 17-18.

Example 23, which describes the “treatment and prevention of thromboembolic disease,” discloses the method of Claim 5. See page 47. Likewise, Example 24, which describes the “reduction of platelet binding to adhesive proteins,” discloses the method of Claim 6. See page 48.

The specification supports Claims 7 and 8, disclosing that a “supplement of  $\gamma$ -tocopherol preferably contains at least 60-65%.” See page 8, line 22. Additionally, page 7 discloses that

“[p]articularly preferred compositions include at least 70%  $\gamma$ -tocopherol,” in support of Claim 9. See page 8, lines 24-25.

The specification also supports Claim 10, disclosing supplying a supplement containing “a formulation of  $\gamma$ -tocopherol 75%.” See page 47, line 17. Additionally, page 8 discloses that “formulations of  $\gamma$ -tocopherol that would be effective for use in the disclosed methods may include as low as 50% (weight to weight)  $\gamma$ -tocopherol or up to 100% (weight to weight)  $\gamma$ -tocopherol, but desirably contain 55% (weight to weight)  $\gamma$ -tocopherol to 95% (weight to weight)  $\gamma$ -tocopherol,” in support of Claims 11-13. See page 8, lines 26-29.

The specification also discloses that a “supplement comprising  $\gamma$ -tocopherol and a  $\gamma$ -tocopherol derivative preferably contains 5% to 95% (weight to weight)  $\gamma$ -tocopherol mixed with 5% to 95%  $\gamma$ -tocopherol derivative,” which supports Claims 14 and 15. See page 22, lines 16-18. Additionally, the specification discloses that  $\gamma$ -tocopherol “may also be administered with physiologically suitable carriers such as, for example, olive oil, sesame oil, or other lipid,” which also provides support to Claim 15. See page 23, lines 5-7.

The specification identifies as “a further embodiment [of the invention] a medicament comprising  $\gamma$ -tocopherol.” Page 3, line 24. Additionally, “[t]he preparation of soft gelatin capsules comprising commercially available  $\gamma$ -tocopherol,” is disclosed. Page 8, lines 19-20. Accordingly, the specification provides support for Claim 16. The specification further discloses that “[t]he compounds can be administered orally or parenterally,” which provides support for Claims 17 and 18. See page 23, line 7.

Example 28 supports Claim 19, disclosing that “[t]he experimental group of vitamin E deficient rats is treated with either 20 mg/kg of  $\gamma$ -tocopherol or a formulation 75% (weight to weight) of  $\gamma$ -tocopherol and 25% (weight to weight) LLU- $\alpha$ .” See page 51.

CONCLUSION

Applicant has fulfilled all the requirements to provoke an interference. Accordingly, examination with special dispatch in accordance with 37 C.F.R. § 1.607(b) is respectfully requested.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12 Sept. 2003

By: Daniel Altman

Daniel E. Altman  
Registration No. 34,115  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

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